

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

22-13

3/22/13

HISTORICAL SALMONELLA SEROTYPE INFORMATION LETTERS FOR ESTABLISHMENTS PRODUCING GROUND CHICKEN AND GROUND TURKEY

I. PURPOSE

This notice announces that FSIS has developed Historical *Salmonella* Serotype Information (HSSI) letters that provide serotype test results for *Salmonella* positive ground chicken and ground turkey samples collected by FSIS. FSIS developed these letters for establishments that produce raw comminuted chicken or turkey products. FSIS collected the samples for the results included in these letters between January 1, 2005 and January 1, 2012. Together with any existing *Salmonella* End of Set letters (EOSL), the HSSI letters will provide, for each establishment, compiled serotype information on all positive FSIS *Salmonella* results. In addition to these letters, FSIS has developed for each establishment an electronic spreadsheet file containing the raw data used as the source of the information in the HSSI letters. FSIS is providing this information so that establishments have it available for their use when they analyze their food safety systems and to help guide establishment decisionmaking.

II. BACKGROUND

A. FSIS's *Salmonella* verification testing program and food safety strategy focus on establishments' overall process control, and particularly on establishments that have had a high percentage of *Salmonella* positive test results (71 FR 9772, February 27, 2006). The Agency has electronically provided individual sample results to establishments as they have become available and, since 2011, as compiled set results in signed EOSL with sample-by-sample serotype information.

B. The Agency has collected a large amount of historical data that has not been provided to industry in a compiled form. Both the Agency and industry agree that this data will be valuable for establishments to have to incorporate it into their decisionmaking processes.

C. The HSSI letter and data set will include information regarding not only positive or negative test results but also serotype information for all positive *Salmonella* results.

D. FSIS identifies the serotype and develops certain subtyping information, including the Pulsed Field Gel Electrophoresis (PFGE) pattern and the antimicrobial resistance profile, for the *Salmonella* isolate from each positive verification sample. FSIS uses the subtyping results to identify historical trends within the sampling data, to determine whether an isolate has a historical association with human illness, and to identify clusters of patterns.

E. FSIS considers that isolates with subtypes historically associated with human illness are more likely to cause human illness than those without such a history. The Agency has said that establishments that repeatedly produce product with *Salmonella* subtypes of public health concern

DISTRIBUTION: Electronic

NOTICE EXPIRES: 4/1/14

OPI: OPPD

are of high priority for a Food Safety Assessment (FSA; see [FSIS Directive 5100.4](#)). FSIS thus considers information on serotypes and subtypes to be very important for protecting the public health. The HSSI letters provide serotype information for establishments' use in their food safety decisionmaking processes.

NOTE: Information on the PFGE and antimicrobial resistance profile will be provided in expanded HSSI letters or separate mailings to the establishment once it is available. A separate FSIS notice will be issued to further explain this additional information.

F. The fact that isolates have subtypes historically associated with human illness does not automatically implicate the sampled product as the cause for any human illness or necessarily mean that the establishment's food safety system is ineffective. FSIS will determine these specific associations through an epidemiological investigation or a FSA.

III. DISCUSSION OF HSSI LETTERS AND SPREADSHEET AT WEEKLY MEETING

A. In establishments that produce comminuted chicken and comminuted turkey products, during the next weekly meeting after the issuance of this notice, IPP are to inform establishment management that:

1. Some establishments will be receiving a detailed HSSI letter and Microsoft Excel spreadsheet file (in electronic format). Not all establishments producing NRTE comminuted poultry will get these letters. Only establishments that had ground chicken or ground turkey samples collected between January 2005 and January 2012 will receive a HSSI letter. The spreadsheet file will contain individual *Salmonella* test results for ground chicken or ground turkey samples collected by FSIS. These sample results were used to develop the tables in the HSSI letter. FSIS is providing the raw data to all establishments that receive the HSSI letter so it is available should an establishment choose to perform additional analyses. The spreadsheet file also contains the two tables that are in the letter.
2. After an establishment receives the letter and spreadsheet, IPP are to briefly review the results provided in the letter with establishment management at the next weekly meeting after receiving the letter and spreadsheet.
3. IPP are to remind the establishment that it should always consider process control and subtyping results in its decisionmaking process when evaluating its overall food safety system and make changes as appropriate. The establishment may find the information in the HSSI letter and spreadsheet useful as it reassesses its HACCP plan, as directed in the *Federal Register* notice [HACCP Plan Reassessment for Not-Ready-to-Eat Comminuted Poultry Products and Related Agency Verification Procedures](#) (77 FR 72686).
4. FSIS may ultimately find that establishments that fail to adequately consider the provided information in their decisionmaking process do not have an effective food safety system.
5. Technical and sampling questions can be directed through *askFSIS* at <http://askfsis.custhelp.com>

NOTE: The FSIS Office of Policy and Program Development will provide the Inspector in Charge/Consumer Safety Inspector, Frontline Supervisor, Deputy District Manager, and District Manager, via email, the HSSI letter and the spreadsheet for the establishment at the same time as it sends them to the establishment. Establishments without an email address will receive a mailed letter and spreadsheet file.

B. As with the EOSL, unless instructed by the District Office, there is no follow-up verification for IPP to perform or enforcement to take based on the information and results provided in the HSSI letter. An Enforcement, Investigation, and Analysis Officer (EIAO) will verify the appropriateness of the establishment's response to the results in the next FSA performed at the establishment.

IV. EIAO RESPONSIBILITIES RELATED TO THE HSSI LETTERS

A. As part of pre-FSA preparation (see [FSIS Directive 5100.1](#)), EIAOs are to obtain the HSSI letter from the District Office for an establishment that produces raw comminuted chicken or turkey. As part of their review of establishment data, EIAOs are to review the information in the establishment's HSSI letter and spreadsheet and evaluate whether there are any trends in *Salmonella* serotypes.

B. If the HSSI letter indicates that there are any trends or patterns in *Salmonella* serotypes, EIAOs are to review other FSIS data to determine whether these trends continue into the 6 - 8 months preceding the EIAO's visit to the establishment. EIAOs are to determine whether establishments are analyzing the information provided in the HSSI letters and spreadsheet to answer the questions in the FSA tools.

V. CONTENT OF HSSI LETTERS

A. A brief description of content of the HSSI letters is included below. (See [Attachment 1: Sample Historical Salmonella Serotype Information Letter](#).) Other than the two tables included in each letter, content of the letters will not differ from what is in this example letter.

B. **Public Health-focused Evaluation of Isolates by Serotype:** This section provides detailed serotyping information from the establishment's historical *Salmonella* verification sets.

1. This section includes the "*Summary of Establishment Sampling*" table, which provides a summary of samples, including number of samples collected and analyzed, number of *Salmonella* positives, and for how many positives the serotype was identified and reported.
2. This section also includes the "*Serotype Results for All Included Sets*" table, which provides the details of the serotype results for all included samples from that establishment and a brief explanation of the type of information provided in the table.

VI. CONTENT OF ESTABLISHMENT DATA SPREADSHEET

A. The Microsoft Excel Spreadsheet electronic file contains the raw data used to develop both tables in the letter. [Attachment 2: Sample establishment data spreadsheet](#) page provides an example for IPP of how data will appear in the electronic spreadsheet. FSIS will provide an electronic file of this data, not a printed copy.

B. Each line on the spreadsheet corresponds to one FSIS HACCP Verification ground turkey or ground chicken sample. For each sample, the following information is provided: product type (ground chicken or ground turkey), establishment number, sample collection date, sample form ID (unique identifier for each sample), sample result (positive or negative for *Salmonella*), and serotype (if *Salmonella* positive). If the samples were collected as part of a set, then the sample set ID, set start date, and set completion date will also be included.

VII. QUESTIONS

Refer questions regarding this notice to the Risk, Innovations, and Management Division through [AskFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter FSIS Notice 22-13
Question Field:	Enter question with as much detail as possible.
Queue Field:	Sampling
Product Field:	Select General Inspection Policy from the drop-down menu.
Category Field:	Select Salmonella from the drop-down menu.
Policy Arena:	Select Domestic (U.S.) Only from the drop-down menu.

When all fields are complete, press the **Submit** button.



Assistant Administrator
Office of Policy and Program Development

Attachment 1: Sample Historical *Salmonella* Serotype Information Letter

This is an example of an HSSI letter with fictitious data to illustrate the sections and content of the letter.

March 26, 2013

Establishment 99999 P
Sunshine Farms
Sunshine City, FL 00000

Dear Establishment P-99999:

This letter is sent to provide compiled available serotype test results for *Salmonella* positive ground (turkey/chicken) samples collected by FSIS between January 1, 2005 and January 1, 2012. You have previously been provided serotype results individually as they have become available and in End of Set Letters after the completion of a set. FSIS will continue to serotype positive samples, provide results individually as they become available, and provide serotype information in future End of Set Letters. The information in this letter, together with information in End of Set Letters, provides you with information on the serotypes that are or have been detected in your establishment. FSIS is providing this information so that you can analyze, such as determining whether there are serotype trends, and use the information to help guide your food safety decisionmaking. If you produce not ready-to-eat comminuted chicken or turkey products, you may find this information useful as you reassess your establishment's HACCP plans (see *Federal Register* notice [HACCP Plan Reassessment for Not-Ready-to-Eat Comminuted Poultry Products and Related Agency Verification Procedures](#) (77 FR 72686)). This information may also be useful any time you are reviewing your food safety decisions and processes for manufacture of comminuted poultry products.

Public Health-focused Evaluation of Isolates by Serotype

FSIS has evaluated the serotypes¹ of the *Salmonella* isolates from samples referenced above and is providing public health-focused information on these isolates. Serotyping, PFGE pattern identification, and antimicrobial susceptibility profiling of bacterial isolates provide added distinction to *Salmonella* isolates from food and environmental samples and from human specimens. This information can be used to better focus food safety efforts to protect public health. Compiled serotypes are provided in this letter to facilitate the establishment's efforts to identify interventions (e.g., pre-harvest) it can use to address these serotypes. PFGE pattern and antimicrobial resistance profile information, to the extent available, will be provided in a separate mailing once it becomes available.

Serotype commonly associated with human illness: These isolates have a serotype that is commonly associated with human illness. The most recent list of the serotypes that are more commonly associated with human illness can be found on the CDC Web site at:
<http://www.cdc.gov/ncidod/dbmd/phlisdata/Salmonella.htm>.

Isolates with a serotype not included on this list have a serotype that is less frequently associated with human illness. Please note that all *Salmonella* serotypes are considered to be capable of causing illness in humans.

¹ Serotypes of positive samples were determined by the National Veterinary Services Laboratory of USDA or by an FSIS Food Safety Laboratory using the CDC molecular serotyping method.

Summary of Establishment Sampling

First Sample Collection Date:	January 15, 2005
Last Sample Collection Date:	July 31, 2011
Total Number of Samples analyzed:	980
Total Number of Positives:	190
Total Serotypes Identified:	185
Total Unidentified	5

Note that some serotypes may be unidentified in some cases due to limitations on retrieving data from older data systems.

Serotype Results for All Included Sets

The table below presents all serotypes isolated from ground (turkey or chicken) sampled from your establishment between January 15, 2005 and July 31, 2011. Column 2 indicates whether the serotype is commonly associated with human illness, as discussed above. Column 3 (number) presents the number of isolates of each serotype. Column 4 (Percentage of *Salmonella* Positive Ground (Turkey or Chicken) samples, establishment's samples) presents the percentage that each serotype represents among *Salmonella* positive samples. Column 5 (Percentage of All Ground (Turkey or Chicken) samples, establishment's samples) presents the percentage that each serotype represents among all samples collected, including negative samples.

1	2	3	4	5
Serotypes detected	Serotype commonly associated with human illness? ²	Number	Percentage of <i>Salmonella</i> Positive Ground (Turkey or Chicken) samples, establishment's samples	Percentage of All Ground (Turkey or Chicken) samples, establishment's samples
Hadar	Yes	65	32.2	7.0
Heidelberg	Yes	19	10.6	2.3
Reading	No	18	7.2	1.6
Saintpaul	Yes	13	7.2	1.6
Newport	Yes	11	6.1	1.3
Senftenberg	No	9	5.0	1.1
Typhimurium	Yes	8	3.3	0.7
Agona	Yes	4	2.8	0.6
Albert	No	4	2.2	0.5
Uganda	No	3	1.7	0.4
Schwarzengrund	Yes	2	1.1	0.2
Istanbul	No	2	1.1	0.2
Alachua	No	2	1.1	0.2
Mbandaka	No	2	1.1	0.2
Anatum	No	1	0.6	0.1
I 4,12:l,v:-	No	1	0.6	0.1
Ohio	No	1	0.6	0.1

² Based on the CDC's most recent (2009) published list of 20 most frequently reported *Salmonella* serotypes from humans (<http://www.cdc.gov/ncidod/dbmd/phlisdata/Salmonella.htm>).

Note that these FSIS data do not indicate the overall prevalence of these serotypes in product but indicate which serotypes have been confirmed present in the product sampled.

FSIS expects establishments to consider serotype results in their decisionmaking process when evaluating the effectiveness of their overall food safety system. This could be accomplished by establishments identifying and implementing relevant pre-harvest and post-harvest strategies. More information on such strategies can be found in available Agency Compliance Guidelines for controlling *Salmonella* and *Campylobacter* on the FSIS Webpage³. FSIS is providing the spreadsheet file (Microsoft Excel) so that data is available should your establishment elect to perform additional evaluations. Data are accurate as of March 2013, when FSIS obtained data from its archive.

Please be advised that an establishment that does not adequately take such information into account in the decisionmaking process when evaluating the effectiveness of its overall food safety system may be determined to have an ineffective food safety system. In addition, if FSIS determines that a product produced by an establishment is associated with human illness because *Salmonella* is present in that product, FSIS may consider the product adulterated and take appropriate regulatory action against the establishment.

Please direct questions to askFSIS (<http://askfsis.custhelp.com>).

Sincerely,

William K. Shaw, Jr.
Director
Risk, Innovations, and Management Division
Office of Policy and Program Development

cc: Inspector-in-Charge (via electronic copy)
 Frontline Supervisor (via electronic copy)
 Deputy District Manager (via electronic copy)
 District Manager (via electronic copy)

³ [http://www.fsis.usda.gov/Regulations_& Policies/Compliance_Guides_Index/index.asp#Salmonella](http://www.fsis.usda.gov/Regulations_&Policies/Compliance_Guides_Index/index.asp#Salmonella).

Attachment 2: Sample establishment data spreadsheet page

Product type	Establishment number	Sample collection date	Sample form ID	Sample Result	serotype	Sample Set ID	Set Start Date	Set Complete Date
Ground Turkey	99999 P	1/4/2010	355339	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/5/2010	355340	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/6/2010	355341	Positive	Heidelberg	18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/7/2010	355342	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/8/2010	355343	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/12/2010	355346	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/13/2010	355347	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/14/2010	355348	Positive	Hadar	18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/15/2010	355349	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/18/2010	355350	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/19/2010	355351	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/20/2010	355352	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/21/2010	355353	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/22/2010	355354	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/25/2010	355355	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/26/2010	355356	Positive	Anatum	18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/27/2010	355357	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/28/2010	355359	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	1/29/2010	355360	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	2/1/2010	355361	Negative		18-12	10/4/2009	2/1/2010
Ground Turkey	99999 P	2/2/2010	355362	Negative		N/A*	N/A*	N/A*
Ground Turkey	99999 P	3/18/2010	355363	Positive	Hadar	N/A*	N/A*	N/A*
Ground Turkey	99999 P	2/28/2011	364578	Negative		19-14	2/28/2011	5/4/2011
Ground Turkey	99999 P	3/1/2011	364579	Negative		19-14	2/28/2011	5/4/2011

* sample was collected outside of a *Salmonella* HACCP verification set or complete set information is not available (for example, for a set that was later cancelled or that was not scheduled as part of a set).